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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,290	04/27/2001	Werner Schobler	0107-031	1048

23464 7590 04/03/2006

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EXAMINER	
KIM, YUNSOO	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/844,290	SCHOBLER ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-45* is/are pending in the application.

4a) Of the above claim(s) *24-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 23-45 are pending.

2. Applicants' Response to Restriction filed on 1/6/06 is acknowledged.

Applicants' election of Group I without traverse, claims 23 and 45 drawn to an anti- petasin antibody and a test kit is acknowledged.

Accordingly, claims 24-44 are withdrawn from the further consideration by examiner 37 CFR.1.142 (b) as being drawn to a non-elected invention.

3. Applicants' claim for foreign priority under 35. U.S.C. 119 (a)-(d) is acknowledged.

4. Applicants' are invited to file an IDS for consideration.

5. It is noted that the non-initialed alteration has been made in the oath filed 3/28/05.

6. It is noted that the p. 6 of the specification contains a blank area. Appropriate correction is required.

7. 35.U.S.C.101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claim 23 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, a product of nature. Claim 23 as written, does not sufficiently distinguish over antibody as it exists naturally because the claim does not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 23 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for anti-petasin antibody, does not reasonably provide enablement for anti-petasin antibody that does not crossreact with petasin derivatives. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification disclosure does not enable one skilled in the art to practice the invention without any undue amount of experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed.Cir.1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of the skilled in the art to practice the claimed invention.

Applicants have claimed an anti-petasin antibody that binds to petasin but does not cross react with petasin derivatives or structural analogs or metabolites to petasin.

It is known in the art that most monoclonal antibodies bind nonspecifically to some extent (Stewart et al., 1997, 4.1.1-4.1.13). This crossreactivity is generally directed to compounds that are structually similar to the target antigen (Wild, Immunology Handbook 2001, p. 83-89).

Furthermore, the specification of the instant application has not tested or disclosed the antibody being free of cross reactive to petasin derivatives, structural analogs, or metabolites of petasin.

Given the lack of guidance or working examples in the specification of an antibody that binds to petasin but does not crossreact with the derivatives and the fact that generating antibodies that lack crossreactivity is unpredictable given the teachings of Stewart et al. and Wild, a skilled artisan would not be able to make or use the claimed invention without undue experimentation.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 23 and 45 are rejected under 35 U.S.C. 103 as being unpatentable over Bickel et al. (Planta Med., 1994, 60:318-322) in view of Campbell (Monoclonal Antibody Technology, 1984, p. 1-31) and U.S. Pat. No. 4,281,061.

Bickel et al. teach a petasin and its structure (abstract, introduction, Fig 3). Bickel et al. disclose the pure form of petasin in sufficient quantities is in need for further research (p. 322, last paragraph).

Bickel et al. does not teach an antibody to petasin and a test kit to detect petasin.

However, Campbell teaches that monoclonal antibody production is a well-established technique in the art, the antibodies can be produced against almost any substance and commonly used in diagnostic uses (p. 17, 29).

Campbell further teaches that the absolute purity of the antigen for monoclonal antibody production is not essential (p. 5, table 1.1) and monoclonal antibody can be used for affinity purification to obtain large quantities of required antigen from the crude mixture (p. 25).

The '061 patent teaches a test kit comprising an antibody (col. 3, lines 19-24), solid phase (e.g. resins, col. 4, lines 2-10), dilution buffer, solution and enzymes (col. 12-24, claims 1-17) as a matter of convenience and to optimize the sensitivity of the assay in the range of the interest (col. 22-23 overlapping paragraph).

Therefore, one of the ordinary skill in the art would have been motivated to combine the antibody production technique as taught by Campbell to produce large quantities of pure antigen (e.g. petasin) in a further research for diagnostic use and combine it as a kit format to maximize the convenience.

From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

13. No claims are allowable.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
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March 27, 2006

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